

MAR 29 2007

REMARKS

Claims 1-46 are currently pending. Of these, claims 39-46 have been withdrawn from consideration pursuant to a restriction requirement.

**I. Restriction Requirement**

The Examiner required restriction between two inventions: (I) Claims 1-38, drawn to a prosthesis system; and (II) Claims 39-46, drawn to a surgical method. In support of the restriction requirement, the Examiner asserted that Applicant's claimed vertebral body facet joint prosthesis system "may be used for other orthopedic applications beyond that of the natural facet joint of the vertebral body." (Examiner's Action at p. 2.) Applicant hereby traverses the restriction requirement.

Claim 1 recites a prosthesis system to replace a natural facet joint between adjoining inferior and superior vertebral bodies comprising a caudal prosthesis accommodating fixation to the inferior vertebral body at or near a pedicle and without support by a lamina, including an artificial caudal facet joint structure adapted and configured to replace all or a portion of a caudal portion of the natural facet joint, and a cephalad prosthesis accommodating fixation to the superior vertebral body at or near a pedicle and without support by a lamina, including an artificial cephalad facet joint structure adapted and configured to replace all or a portion of a cephalad portion of the natural facet joint and to articulate with the artificial caudal facet joint structure, thereby forming an artificial facet joint between the adjoining vertebral bodies. Claim 39 recites a method of replacing a natural facet joint between adjoining inferior and superior vertebral bodies *using the prosthesis system defined in claim 1* to provide improved support for the spinal column, the method comprising the steps of (i) removing from the inferior vertebral body all or a portion of a caudal portion of the natural facet joint, (ii) removing from the superior vertebral body all or a portion of a cephalad portion of the natural facet joint, (iii) fixing the caudal prosthesis *as defined in claim 1* to the inferior vertebral body to replace the removed caudal portion of the natural facet joint with the artificial caudal facet joint structure, (iv) fixing the cephalad prosthesis *as defined in claim 1* to the superior vertebral body to replace the removed cephalad portion of the natural facet joint with the artificial cephalad facet joint

Attorney Docket 10002-701.410

- 10 of 12 -

Response dated: March 29, 2007  
Appln. No. 10/658,651; Filed: September 9, 2003  
Reply to Restriction Requirement of January 29, 2007

structure, and (v) affecting articulation between the artificial caudal facet joint structure and the artificial cephalad facet joint structure to create an artificial facet joint between the adjoining vertebral bodies (emphasis added). The Examiner's position that the vertebral body facet joint prosthesis system of claim 1 may be used for other orthopedic applications beyond that of the natural facet joint of the vertebral body despite the literal structural limitations recited by the claim is factually absurd and is an improper use of the restriction process. Applicant respectfully requests that the restriction requirement be withdrawn.

Notwithstanding Applicant's traversal of the requirement, Applicant hereby elects invention I, claims 1-38. Claims 39-46 have been provisionally indicated as being withdrawn from consideration pending resolution of the Examiner's improper restriction requirement. Applicant reserves the right pursuant to 35 U.S.C. § 121 to file one or more divisional applications directed to the non-elected invention during the pendency of the present application.

## **II. Election Requirement**

The Examiner stated that the application contains claims directed to patentably distinct species and required Applicants to elect one of them. The Examiner stated further that no claims are generic. In fact, however, many of the "species" the Examiner listed are not claimed at all. All claims are drawn to prosthesis systems to replace a natural facet joint between adjoining inferior and superior vertebral bodies comprising caudal and cephalad prostheses accommodating fixation to the inferior or superior vertebral bodies, respectively, and methods of using such prosthesis systems. Figures 2, 2A, 2B, 2C, 20, 22, 29, 32, 34, 36, 37, 38, 39, 41 and 42 do not even show prosthesis systems comprising caudal and cephalad prostheses accommodating fixation to inferior and superior vertebral bodies, respectively. Furthermore, apparatus claims 1-38 and method claims 39-46 are generic to all claimed species, despite the Examiner's assertion to the contrary.

37 CFR 1.146 gives the Examiner the authority to require an election of species when the case has claims drawn to more than a reasonable number of species. In this case, the Examiner appears to have made no effort to determine whether all of the figures in his list of "species"

RECEIVED  
CENTRAL FAX CENTER

MAR 29 2007

Response dated: March 29, 2007  
Appl. No. 10/658,651; Filed: September 9, 2003  
Reply to Restriction Requirement of January 29, 2007

actually had claims drawn to them. The Examiner has therefore not met the requirements of Rule 146. For these reasons, Applicant traverses the Examiner's election of species requirement.

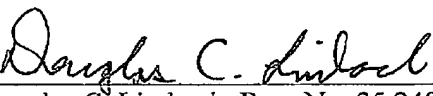
Notwithstanding Applicant's traversal of the requirement, Applicant hereby elects the species identified by the Examiner as Figure 24. Apparatus claims 1-38 and method claims 39-46 read on this species. Applicant reserves the right pursuant to 35 U.S.C. § 121 to file one or more divisional applications directed to the non-elected species during the pendency of the present application.

#### CONCLUSION

Applicant submits that this paper fully addresses the Office Action mailed January 29, 2007. Should the Examiner have any questions, the Examiner is encouraged to contact the undersigned attorney at 650.212.1700.

Respectfully submitted,

Dated: March 29, 2007

  
Douglas C. Limbach, Reg. No. 35,249

SHAY LAW GROUP LLP  
2755 Campus Drive, Suite 210  
San Mateo, CA 94403  
Telephone: 650.212.1700  
Facsimile: 650.212.7562